

## Message Text

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17

ORIGIN HEW-08

INFO OCT-01 ARA-16 EUR-25 EA-11 ISO-00 SCI-06 NSF-04 RSC-01

/072 R

66612

DRAFTED BY:DHEW/FDA:LRSHELTON

APPROVED BY:SCI/SA:MSBEAUBIEN

EUR/CE:LHEICHLER EA/ANP:HLANGE EUR/NE:CFLOYD

ARA/MEX:JRHAMILTON EUR/WE:EJBEIGEL EA/J:CDUNKERLY

DHEW/OIH:MACODDING

----- 077639

R 272349Z AUG 74

FM SECSTATE WASHDC

TO AMEMBASSY BONN

AMEMBASSY CANBERRA

AMEMBASSY LONDON

AMEMBASSY MEXICO

AMEMBASSY PARIS

AMEMBASSY TOKYO

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E.O. 11652: N/A

TAGS: TBIO, XG, MX, JA, AS

SUBJECT: REVISION OF OPERATING INSTRUCTIONS - ABBOTT BIOCHROMATIC  
ANALYZER

1. FDS ADVISES THAT ABBOTT LABS, DIVISIONAL OFFICE, 820 MISSION  
ST., SOUTH PASADENA, CALIF. HAS UNCOVERED TWO PROBLEMS WITH ABBOTT  
BIOCHROMATIC ANALYZER, MODEL ABA-100 AND MODEL ABA-50. ARE USED  
FOR DIAGNOSES AT CLINICAL AND RESEARCH LABORATORIES.

2. THERE ARE TWO SEPARATE PROBLEMS EACH OF WHICH MAY CAUSE  
SERIOUSLY LOW READINGS FOR BLOOD GLUCOSE:

#1 - ERROR IN INSTRUCTION MANUAL FOR ABA-100 AND A LACK OF PROPER  
DIRECTIONS FOR ABA-50 MAY RESULT IN INCORRECT PLACEMENT OF DECIMAL  
POINT IN ASSAYS, RESULTING IN LOSS OF FIRST DIGIT IN READ-OUT;

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THUS, A BLOOD GLUCOSE LEVEL OF 1043 MG COULD BE READ AS 043.0

MG.

#2 - BOTH DEVICES RESPOND IN GROSSLY NON-LINEAR MANNER FOR SAMPLES WELL IN EXCESS OF 1000 MG BLOOD GLUCOSE. READ-OUT AT THESE LEVELS MAY FALL AT OR EVEN BELOW THE NORMAL RANGE OF 75-115 MG.

3. FIRM IN JULY ADVISED PRIMARY CONSIGNEES, ISSUING CORRECTIONS IN OPERATING MANUALS AND REQUESTED LISTING OF SECONDARY CONSIGNEES FOR FOLLOW-UP.

4. OVERSEAS CONSIGNEES:

ENGLAND  
COULTER SCIENTIFIC LTD.  
COLDHARBOUR LANE, HAPPENDEN, HERTFORDSHIRE

FRANCE  
COULTER SCIENTIFIC S.A.  
14 RUE EUGENE-LEGENDRE  
MARGENCY, ANDILLY

GERMANY  
COULTER-SCIENTIFIC GMBH  
415 KREFELD, HULSER STRASSE 295

AUSTRALIA  
ABBOTT AUSTRALASIA PTY. LTD.  
CAPTAIN COOK DRIVE  
KURNELL, N.S.W.

JAPAN  
DAINABOT RADIOISOTOPE LAB. LTD.  
2-8 HATCHOBORI 1-CHOME, CHUO-KU  
TOKYO

MEXICO  
LABORATORIOS BIOAUTOMATIZADOS, S.A.  
TIJUANA

LABORATORIOS CLINICOS ESPECIALIZADOS  
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1004 GONZALITOS  
MONTERREY

5. POSTS REQUESTED TO CHECK TO ASSURE THAT CONSIGNEES HAVE RECEIVED INSERTS RELATING TO MANUAL CORRECTIONS, THAT MANUALS HAVE BEEN REVISED, AND THEY UNDERSTAND THE TWO PROBLEMS INVOLVED WITH THE DEVICES. KISSINGER

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NNN

## Message Attributes

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**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
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**TAGS:** TBIO, XG, MX, JA, AS, ABBOTT  
**To:** BONN MULTIPLE  
**Type:** TE  
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